



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/997,855

11/29/2001

Jerome Segal

70802.01

6694

22509

7590

09/30/2003

MICHAEL E. KLICPERA  
PO BOX 573  
LA JOLLA, CA 92038-0573

EXAMINER

MAYNARD, JENNIFER J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/997,855

Applicant(s)

SEGAL ET AL.

Examiner

Jennifer J Maynard

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restriction***

***Election of Species***

Claims 1-13 and 31-34 are generic to a plurality of disclosed patentably distinct species comprising:

Species I, representative of an apparatus for mechanically dilating and passively delivering medicament to an obstruction.

Species II, representative of an apparatus for mechanically dilating and utilizing iontophoresis and/or electroporation for delivering a medicament to an obstruction.

Species III, representative of a rapid exchanged designed mechanical dilatation and medicament delivery device.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Election of Subspecies***

Once Applicant elects either Species I or II, then the following election of a primary subspecies and a secondary subspecies is required.

Art Unit: 3763

Claims 1-13 and 31-34 are generic to a plurality of disclosed primary subspecies comprising:

Primary Subspecies A, depicted in Figure 13.

Primary Subspecies B, depicted in Figure 14.

Primary Subspecies C, depicted in Figure 15.

Claims 1-13 and 31-34 are generic to a plurality of disclosed patentably distinct secondary subspecies comprising:

Secondary Subspecies 1, depicted in Figure 11.

Secondary Subspecies 2, depicted in Figure 12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed primary subspecies and a single disclosed secondary subspecies, even though this requirement is traversed.

Should applicant traverse on the ground that the primary subspecies and the secondary subspecies are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the primary subspecies and the secondary subspecies to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Supplemental Election of Subspecies***

Additionally, if Applicant were to elect Species II, then the following supplemental election of subspecies is required.

Claims 1-13 and 31-34 are generic to a plurality of disclosed patentably distinct subspecies comprising:

Subspecies I, depicted in Figure 8A.

Subspecies II, depicted in Figure 8B.

Subspecies III, depicted in Figure 8C.

Subspecies IV, depicted in Figure 8D.

Subspecies V, depicted in Figure 8E.

Subspecies VI, depicted in Figure 8F.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed subspecies, even though this requirement is traversed.

Should applicant traverse on the ground that the subspecies are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the subspecies to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### ***Election of Subspecies***

Additionally, if Applicant were to elect Species II, elects a primary subspecies, a secondary subspecies and supplemental subspecies (if applicable), then the following election of subspecies is required.

This application contains claims directed to the following patentably distinct subspecies of the claimed invention:

Art Unit: 3763

Subspecies AA, iontophoretic means, claims 35-38.

Subspecies BB, electroporation means, claims 39-40.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-13 and 31-34 generic.

Applicant is advised that a reply to this requirement must include an identification of the subspecies that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional subspecies which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected subspecies. MPEP § 809.02(a).

Should applicant traverse on the ground that the subspecies are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the subspecies to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following Figure(s) or Figure label(s) mentioned in the description: On Page 14 of Applicant's specification, Figures 2a, 3a, 5a and 6a are described however in Applicant's preliminary amendment mailed 25 September 2002, the brief descriptions of those Figures were deleted and the drawings were amended to replace the existing drawing labels with new ones, as follows: Figure 2a, now Figure 2; Figure 3a, now Figure 3; Figure 5a, now Figure 5a; and Figure 6a, now Figure 6. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following Figure(s) or Figure label(s) not mentioned in the description: Figures 2, 3, 5 and 6. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: (35) on Page 33 of Applicant's specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Art Unit: 3763

***Conclusion***

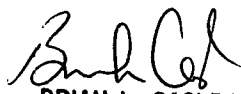
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356.

The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard  
22 September 2003



BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700